

**REMARKS**

In accordance with the foregoing, claims 1 and 5 have been amended. Claim 6 has been cancelled. Therefore claims 1-5 and 7-15 are pending, and claims 1-5, 7-8, and 11-15 are under consideration, which is respectfully requested.

**(A) Amendment to the claims**

In order to more clearly define the present invention, claim 1 has been amended so that the unhydrogenated copolymer recited therein is limited to a block copolymer which is at least one polymer selected from the group consisting of copolymers which are, respectively, represented by the formulae (2) to (6) and (8) to (10) recited in current claim 6.

Support for the amendment to claim 1 is found at page 28, line 25 to page 29, line 18 of the specification.

In accordance with the amendment to claim 1, claim 5 has been amended and claim 6 has been canceled.

In the instant amendment, no new matter has been introduced.

**(B) The state of the art and the essential features and advantages of the present invention**

Before specifically addressing the Examiner's rejections in the outstanding Office Action, it is believed that the following background information should be considered in order to shed a proper light on the development of the present invention and the essential features and advantages thereof.

As described in the present specification under "Prior Art", with respect to a shaped article containing a hydrogenated copolymer which is obtained by hydrogenating an unhydrogenated copolymer comprising vinyl aromatic monomer units and conjugated diene monomer units, it is desired to impart thereto flexibility, low temperature characteristics (such as flexibility at low temperatures), shock-absorbing property (low impact resilience) and compression set resistance, so that the shaped article can be advantageously used as a shock-absorber or the like.

In this situation, the present inventors have made extensive and intensive studies with a view toward developing a shaped article containing the above-mentioned hydrogenated copolymer, wherein the shaped article exhibits excellent properties with respect to flexibility, low temperature characteristics (such as flexibility at low temperatures), shock-absorbing property (low impact resilience) and compression set resistance. As a result, it has unexpectedly been found that such an excellent shaped article can be realized by a polymer foam as defined in amended claim 1 of the present application. For easy reference, amended claim 1 of the present application is reproduced below.

1. (currently amended) A polymer foam comprising a plurality of cells defined by cell walls which constitute a polymer matrix,  
 said polymer matrix being comprised of:  
 5 to 100 parts by weight, relative to 100 parts by weight of the total of components (A) and (B), of (A) a hydrogenated copolymer obtained by hydrogenating an unhydrogenated copolymer, said unhydrogenated copolymer being a block copolymer containing at least one copolymer block S comprised of vinyl aromatic monomer units and conjugated diene monomer units and at least one homopolymer block H of vinyl aromatic monomer units, wherein said at least one copolymer block S has a vinyl bond content of from 5 % to less than 40 % as measured with respect to conjugated diene monomer units, wherein said unhydrogenated copolymer is at least one polymer selected from the group consisting of copolymers which are, respectively, represented by the following formulae (2) to (6) and (8) to (10):

- (2) S-H,
- (3) S-H-S,
- (4) (S-H)<sub>m</sub>-X,
- (5) (S-H)<sub>n</sub>-X-(H)<sub>p</sub>,
- (6) H-S-H,
- (8) H-S-E,
- (9) E-S-H-S and
- (10) (E-S-H)<sub>m</sub>-X

wherein each S independently represents a copolymer block comprised of vinyl aromatic monomer units and conjugated diene monomer units, each H independently represents a homopolymer block of vinyl aromatic monomer units, each E independently represents a homopolymer block of conjugated diene monomer units, each X independently represents a residue of a coupling agent, each m independently represents an integer of 2 or more, and each of n and p independently represents an integer of 1 or more, and

95 to 0 part by weight, relative to 100 parts by weight of the total of components (A) and (B), of (B) at least one polymer selected from the group consisting of an olefin polymer other than said hydrogenated copolymer (A) and a rubbery polymer other than said hydrogenated copolymer (A),  
 said hydrogenated copolymer (A) having the following characteristics (1) and (2):

(1) said hydrogenated copolymer (A) has a content of said vinyl aromatic monomer units of from more than 40 % by weight to 60 % by weight, based on the weight of said hydrogenated copolymer (A), and

(2) at least one peak of loss tangent ( $\tan\delta$ ) is observed at -40 °C to lower than -10 °C in a dynamic viscoelastic spectrum obtained with respect to said hydrogenated copolymer (A),

said polymer foam having a specific gravity of from 0.05 to 0.5.

As seen from amended claim 1 reproduced above, the polymer foam of the present invention contains a hydrogenated copolymer (A) obtained by hydrogenating an unhydrogenated copolymer. The hydrogenated copolymer (A) has the following features (I) to (IV):

(I) The unhydrogenated copolymer from which the hydrogenated copolymer (A) is obtained by hydrogenation is a block copolymer containing at least one copolymer block S comprised of vinyl aromatic monomer units and conjugated diene monomer units and at least one homopolymer block H of vinyl aromatic monomer units, and has a specific block configuration, such as "H-S-H".

(II) The at least one copolymer block S has a vinyl bond content of from 5 % to less than 40 % as measured with respect to conjugated diene monomer units.

(III) The hydrogenated copolymer (A) has a content of the vinyl aromatic monomer units of from more than 40 % by weight to 60 % by weight, based on the weight of the hydrogenated copolymer (A).

(IV) At least one peak of loss tangent ( $\tan\delta$ ) is observed at -40 °C to lower than -10 °C in a dynamic viscoelastic spectrum obtained with respect to the hydrogenated copolymer (A).

By the use of the hydrogenated copolymer having the above-mentioned features (I) to (IV), the polymer foam of the present invention exhibits excellent properties with respect to all of flexibility, low temperature characteristics (such as flexibility at low temperatures), shock-absorbing property (low impact resilience) and compression set resistance. The effects of the present invention are shown in the working examples of the present application.

It should be noted that, by the use of the hydrogenated copolymer (A) recited in amended claim 1, there can for the first time be obtained a polymer foam which exhibits excellent properties with respect to all of flexibility, low temperature characteristics (such as flexibility at low temperatures), shock-absorbing property (low impact resilience) and compression set resistance. In other words, if, for example, the hydrogenated copolymer does not have feature

(IV) (i.e., the feature on the peak of loss tangent), the effect of the present invention cannot be achieved any longer.

In order to substantiate this, Mr. Syuji YAHIRO, a researcher of the Assignee Company, has instantly conducted two additional experiments (referred to as "Additional Experiment 1" and "Additional Experiment 2", respectively), and has made observations with reference to Additional Experiments 1 and 2 as well as Example 1 of the present application. The method and results of the observations are as described in Exhibit 1 accompanying the YAHIRO Declaration. Mr. YAHIRO is well familiar with the present invention.

In Example 1, Additional Experiment 1 and Additional Experiment 2, polymers 1,  $\alpha$  and  $\beta$  are respectively used as the hydrogenated copolymer. Polymer 1 has all of features (I) to (IV). On the other hand, polymer  $\alpha$  has features (I) to (III), but does not have feature (IV); in polymer  $\alpha$ , the peak of loss tangent is observed at -42 °C, which is lower than the lower limit (-40 °C) of the range defined in feature (IV). Further, polymer  $\beta$  has features (I) to (III), but does not have feature (IV); in polymer  $\beta$ , the peak of loss tangent is observed at 12 °C, which is higher than the upper limit (-10 °C) of the range defined in feature (IV).

From the results of Exhibit 1, it can be fairly concluded:

(1) that the polymer foam of Example 1 exhibits excellent properties with respect to all of flexibility, low temperature characteristics (such as flexibility at low temperatures), shock-absorbing property (low impact resilience) and compression set resistance, because the polymer foam is produced using polymer 1 encompassed by the hydrogenated copolymer (A) recited in amended claim 1;

(2) that, on the other hand, the polymer foam of Additional Experiment 1 exhibits poor shock-absorbing property, because the polymer foam is produced using polymer  $\alpha$ , which is not encompassed by the hydrogenated copolymer (A) recited in amended claim 1 in that the peak of loss tangent is observed at -42 °C, which is lower than the lower limit (-40 °C) of the presently claimed range;

(3) that, further, the polymer foam of Additional Experiment 2 exhibits poor low temperature characteristics (such as flexibility at low temperatures), because the polymer foam is produced using polymer  $\beta$ , which is not encompassed by the hydrogenated copolymer (A) recited in amended claim 1 in that the peak of loss tangent is observed at 12 °C, which is higher than the upper limit (-10 °C) of the presently claimed range; and

(4) that, therefore, by the use of the hydrogenated copolymer (A) recited in amended claim 1, there can for the first time be obtained a polymer foam which exhibits excellent properties with respect to all of flexibility, low temperature characteristics (such as flexibility at low temperatures), shock-absorbing property (low impact resilience) and compression set resistance.

### **(C) Rejections based on prior art**

In the outstanding Office Action, claim 1 as well as other claims is rejected under 35 U.S.C. §102(a) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Karande et al. [WO 02/068529 A2] (hereinafter referred to as "Karande '529"), and evidenced by Hawkins et al. [US 3935176] (hereinafter referred to as "Hawkins '176") (see item 5 appearing at pages 3-5 of the Office Action). The Examiner also relies upon US Patent No. 5,191,024 to Shibata et al. in separately rejecting claims 7 and 8. The Applicants disagree with the Examiner and wish to traverse as follows.

#### **(C-1) Karande '529**

Karande '529 is directed to a fabricated article prepared from a blend containing 0 to 50 % by weight of a hydrogenated random styrene/butadiene copolymer (see page 3, lines 3-29 of Karande '529). The Examiner thinks that the hydrogenated random styrene/butadiene copolymer recited in Karande '529 corresponds to the hydrogenated copolymer (A) used in the present invention. More specifically, according to the Examiner, the hydrogenated random styrene/butadiene copolymer recited in Karande '529 corresponds to a hydrogenated block copolymer obtained by hydrogenating a copolymer consisting of only one block comprised of vinyl aromatic monomer units and conjugated diene monomer units.

However, by the instant amendment to claim 1, the embodiment in which the hydrogenated copolymer (A) is obtained by hydrogenating such a copolymer has been removed from the subject matter for which protection is sought in the present application. In amended claim 1 of the present application, the copolymer before hydrogenation is a block copolymer containing not only at least one copolymer block S comprised of vinyl aromatic monomer units and conjugated diene monomer units but also at least one homopolymer block H of vinyl aromatic monomer units (see feature (I) of the hydrogenated copolymer (A)).

Also, Karande '529 has no teaching about any of features (II) to (IV) of the hydrogenated copolymer (A). Especially, regarding feature (IV), Karande '529 is silent about the peak of loss tangent of a polymer.

Regarding feature (IV), the Examiner asserts that "the peak loss tangent is deemed to be inherent to the same chemistry of hydrogenated component (A)" (see page 4, lines 10-11 of the Office Action). However, the Examiner's assertion is not correct.

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999); MPEP 2112 IV.

Applicants have demonstrated both the non-inherency of peak loss and the unexpected benefits of having a peak loss within the claimed range through experimental data. As explained above in connection with Exhibit 1 accompanying the YAHIRO Declaration, polymers 1,  $\alpha$  and  $\beta$  used for producing polymer foams have features (I) to (III) of the hydrogenated copolymer (A). However, with respect to feature (IV) (i.e., the feature that at least one peak of loss tangent ( $\tan\delta$ ) is observed at  $-40^{\circ}\text{C}$  to lower than  $-10^{\circ}\text{C}$ ), only polymer 1 has this feature; specifically, the temperatures at which the peak of loss tangent is observed are  $-15^{\circ}\text{C}$  (polymer 1),  $-42^{\circ}\text{C}$  (polymer  $\alpha$ ) and  $12^{\circ}\text{C}$  (polymer  $\beta$ ). This means that a hydrogenated copolymer having features (I) to (III) does not always have feature (IV). Accordingly, feature (IV) is never inherent to a polymer having features (I) to (III).

Therefore, the hydrogenated random styrene/butadiene copolymer recited in Karande '529 never corresponds to the hydrogenated copolymer (A) recited in amended claim 1.

Further, Karande '529 does not teach or suggest that, by the use of the hydrogenated copolymer (A) recited in amended claim 1, there can for the first time be obtained a polymer foam which exhibits excellent properties with respect to all of flexibility, low temperature characteristics (such as flexibility at low temperatures), shock-absorbing property (low impact resilience) and compression set resistance.

From the above, it is apparent that Karande '529 has no teaching or suggestion about the polymer foam of the present invention and the effect achieved thereby.

**(C-2) Hawkins '176**

The Examiner asserts that Hawkins '176 discloses a thermoplastic elastomeric material comprising a hydrogenated copolymer obtained by hydrogenating an unhydrogenated random copolymer of at least one conjugated diene and at least one vinyl aromatic compound, wherein the unhydrogenated random copolymer has a vinyl aromatic monomer unit content (styrene content) within a specific range (see Abstract of Hawkins '176). (It should be noted that, as described at page 20, lines 2-9 of the present specification, the content of the vinyl aromatic monomer units in the hydrogenated copolymer is approximately equal to the content of the vinyl aromatic monomer units in the unhydrogenated copolymer and, therefore, the content of the vinyl aromatic monomer units in the unhydrogenated copolymer can be used as the content of the vinyl aromatic monomer units in the hydrogenated copolymer.)

The hydrogenated copolymer recited in Hawkins '176 is completely different from the hydrogenated copolymer (A) recited in amended claim 1. Specifically, for example, the copolymer before hydrogenation in Hawkins '176 is a random copolymer, whereas, as explained above, the copolymer before hydrogenation in the present invention is a block copolymer containing not only at least one copolymer block S comprised of vinyl aromatic monomer units and conjugated diene monomer units but also at least one homopolymer block H of vinyl aromatic monomer units.

Also, Hawkins '176 does not teach or suggest that, by the use of the hydrogenated copolymer (A) recited in amended claim 1, there can for the first time be obtained a polymer foam which exhibits excellent properties with respect to all of flexibility, low temperature characteristics (such as flexibility at low temperatures), shock-absorbing property (low impact resilience) and compression set resistance. Especially, Hawkins '176 does not refer to the peak of loss tangent of a polymer, let alone the effect achieving by controlling the peak of loss tangent within a specific range.

The Examiner has not made a *prima facie* case of obviousness. The Examiner asserts that the hydrogenation ratio of the hydrogenated copolymer, the vinyl aromatic monomer unit content of the hydrogenated copolymer, and the vinyl bond content of the diene portion in the unhydrogenated copolymer are "result-effective variables for desired properties for various end uses" and "workable ranges of composition variables are deemed to be either anticipated, or obvious routine optimizations to one of ordinary skill in the art, as evidenced by Hawkins, motivated by the desire to provide the desired properties for the same end uses as the claimed

invention" (see page 3, line 4 from bottom to page 4, line 10 of the Office Action). The Applicants disagree with the Examiner.

The MPEP stipulates that "a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation" (emphasis added) (see MPEP §2144.05, II B). However, the Examiner fails to properly demonstrate that the variables referred to in Hawkins '176 are result-effective variables for achieving the effect of the present invention.

The properties desired to be achieved in Hawkins '176 are completely different from the properties desired to be achieved in the present invention. Specifically, Hawkins '176 intends to obtain a thermoplastic elastomeric material having good thermoplastic elastomeric properties, specifically, good tensile strength and good elongation set (see, column 3, lines 15-25 and 44-54 and column 4, lines 5-25 of Hawkins '176). On the other hand, the present invention intends to obtain a polymer foam having excellent properties with respect to flexibility, low temperature characteristics (such as flexibility at low temperatures), shock-absorbing property (low impact resilience) and compression set resistance. In this connection, it should be noted that the present invention manipulates the vinyl bond content to impart excellent shock-absorbing property (low impact resilience) to the polymer foam (see page 32, line 4-19 of the present specification), and manipulates the vinyl aromatic monomer unit content of the hydrogenated copolymer to impart excellent flexibility and excellent shock-absorbing property (low impact resilience) to the polymer foam (see page 19, line 22 to page 20, line 1 of the present specification).

If the same property is separately optimized to achieve two different goals, one would expect that the optimization results would be different. For example, optimizing a fuel injection system to achieve greater horsepower would achieve a different result from optimizing the fuel injection system to achieve improved gas mileage. Therefore, with respect to each of the vinyl bond content and the vinyl aromatic monomer unit content, the desired range would naturally be different between the Hawkins '176 and the present invention.

In this connection, it should be noted that the argument of Hawkins '176 for achieving good tensile strength actually teaches away the present invention. Attention is drawn to Fig. 2 of Hawkins '176, which shows that the tensile strength of a copolymer consisting of styrene and butadiene is highest when the copolymer has a styrene content of about 5 mol %. In the copolymer, the styrene content of 5 mol % corresponds to the styrene content of 9 wt %, which

is apparent from the following calculation:  $(104 \times 5)/(104 \times 5 + 54 \times 95) = 0.09$ , wherein it should be noted that the molecular weights of styrene and butadiene are 104 and 54, respectively. The styrene content of 9 wt % is outside the range (from more than 40 % by weight to 60 % by weight) defined in feature (III) of the hydrogenated copolymer (A). Therefore, Fig. 2 of Hawkins '176 teaches away the present invention.

Thus, the variables referred to in Hawkins '176 are not result-effective variables for achieving the effect of the present invention.

For the Examiner's reference, a paper titled "The Rise of the Result-Effective Variable" by Moshe K. Wilensky is submitted herewith as "Exhibit 2". Exhibit 2 explains result-effective variables in depth (see heading "What Is a Result-Effective Variable Rejection?" appearing at page 42 of Exhibit 2), and explains their relationship to the *prima facie* case of obviousness (see heading "Traversing Result-Effective Variable Rejections Based on Current Paragraph" at page 43. Exhibit 2 also cites two examples of recent USPTO rejections that improperly asserted that a feature was a result-effective variable (see Examples 1 and 2). It is believed that Exhibit 2 supports the Applicants' argument.

From the above, it is apparent that Hawkins '176 has no teaching or suggestion about the polymer foam of the present invention and the effect achieved thereby.

Thus, the polymer foam of amended claim 1 of the present application has novelty and unobviousness over Karande '529, even if Hawkins '176 is taken into consideration.

Shibata et al. is cited only for an amine functional group bonded to the hydrogenated styrene/butadiene copolymer. Shibata et al. does not compensate for the deficiencies discussed above with regard to Karande '529 and Hawkins '176.

Now that the novelty and unobviousness of amended claim 1 over the prior art has been established, the novelty and unobviousness of the remaining claims over the prior art is also apparent.

#### **(E) Conclusion**

From the foregoing, it is firmly believed that all of the Examiner's rejections have been overcome. Early and favorable action is respectfully solicited.

There being no further outstanding objections or rejections, it is submitted that the application is in condition for allowance. An early action to that effect is courteously solicited.

Finally, if there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned to attend to these matters.

If there are any additional fees associated with filing of this Amendment, please charge the same to our Deposit Account No. 19-3935.

Respectfully submitted,

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Exhibit 1

Observations to show that, by the use of the hydrogenated copolymer (A) recited in amended claim 1, there can for the first time be obtained a polymer foam which exhibits excellent properties with respect to all of flexibility, low temperature characteristics (such as flexibility at low temperatures), shock-absorbing property (low impact resilience) and compression set resistance

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**1. Object of observations**

The object of the observations is to show, with reference to the below-mentioned two additional experiments as well as Example 1 of the present application, that, by the use of the hydrogenated copolymer (A) recited in amended claim 1, there can for the first time be obtained a polymer foam which exhibits excellent properties with respect to all of flexibility, low temperature characteristics (such as flexibility at low temperatures), shock-absorbing property (low impact resilience) and compression set resistance.

**2. Two additional experiments**

Two additional experiments (hereinafter referred to as "Additional Experiment 1" and "Additional Experiment 2", respectively) were instantly conducted as follows.

### Additional Experiment 1

An unhydrogenated copolymer was obtained in substantially the same manner as in the production of polymer 1 described at page 89, line 2 to page 91, line 21 of the present specification, except that the amounts of monomers (i.e., butadiene and styrene) fed to the reaction vessel were changed as follows: the amount of styrene fed to the reaction vessel for the first polymerization reaction was 24 parts by weight; the amounts of butadiene and styrene, fed to the reaction vessel for the second polymerization reaction, were 48 parts by weight and 5 parts by weight, respectively; and the amount of styrene fed to the reaction vessel for the third polymerization reaction was 23 parts by weight.

The obtained unhydrogenated copolymer had a styrene monomer unit content of 52 % by weight, a styrene polymer block content of 47 % by weight, and a vinyl bond content of 20 % by weight as measured with respect to the butadiene monomer units in the unhydrogenated copolymer. Further, the unhydrogenated copolymer had a weight average molecular weight of 130,000.

A hydrogenation reaction was performed in substantially the same manner as in the production of polymer 1, thereby obtaining a hydrogenated copolymer (hereinafter, this copoly-

mer is referred to as "polymer  $\alpha$ ").

Polymer  $\alpha$  had a hydrogenation ratio of 98 %. Further, in a dynamic viscoelastic spectrum obtained with respect to polymer  $\alpha$ , a peak of  $\tan\delta$  was observed at -42 °C.

A polymer foam was produced in substantially the same manner as in Example 1 of the present application (see page 98, line 10 to page 99, line 22 of the present specification), except that polymer  $\alpha$  was used instead of polymer 1. Thus, the polymer foam contained 70 part by weight of polymer  $\alpha$  and 30 parts by weight of rubbery polymer 1 described at page 95, line 9 to page 98, line 8 of the present specification.

Properties of the polymer foam were measured in accordance with the methods described in the present specification (see page 84, line 19 to page 87, line 18 of the present specification). The results are as follows:

Specific gravity: 0.23

Hardness at 22 °C: 50

Hardness at -10 °C: 49

Impact resilience (%): 46

Compression set (%): 43

#### Additional Experiment 2

An unhydrogenated copolymer was obtained in substan-

tially the same manner as in the production of polymer 1 described at page 89, line 2 to page 91, line 21 of the present specification, except that the amounts of monomers (i.e., butadiene and styrene) fed to the reaction vessel were changed as follows: the amount of styrene fed to the reaction vessel for the first polymerization reaction was 6 parts by weight; the amounts of butadiene and styrene, fed to the reaction vessel for the second polymerization reaction, were 41 parts by weight and 47 parts by weight, respectively; and the amount of styrene fed to the reaction vessel for the third polymerization reaction was 6 parts by weight.

The obtained unhydrogenated copolymer had a styrene monomer unit content of 59 % by weight, a styrene polymer block content of 12 % by weight, and a vinyl bond content of 19 % by weight as measured with respect to the butadiene monomer units in the unhydrogenated copolymer. Further, the unhydrogenated copolymer had a weight average molecular weight of 160,000.

A hydrogenation reaction was performed in substantially the same manner as in the production of polymer 1, thereby obtaining a hydrogenated copolymer (hereinafter, this copolymer is referred to as "polymer  $\beta$ ").

Polymer 2 had a hydrogenation ratio of 99 %. Further, in

a dynamic viscoelastic spectrum obtained with respect to polymer  $\beta$ , a peak of  $\tan\delta$  was observed at 12 °C.

A polymer foam was produced in substantially the same manner as in Example 1 of the present application (see page 98, line 10 to page 99, line 22 of the present specification), except that polymer  $\beta$  was used instead of polymer 1. Thus, the polymer foam contained 70 part by weight of polymer  $\beta$  and 30 parts by weight of rubbery polymer 1 described at page 95, line 9 to page 98, line 8 of the present specification.

Properties of the polymer foam were measured in accordance with the methods described in the present specification (see page 84, line 19 to page 87, line 18 of the present specification). The results are as follows:

Specific gravity: 0.23

Hardness at 22 °C: 45

Hardness at -10 °C: 70

Impact resilience (%): 5

Compression set (%): 55

### 3. Observations

In Example 1 of the present application and above-conducted Additional Experiments 1 and 2, polymer foams containing hydrogenated copolymers are produced, and properties

of the polymer foams are measured (see page 98, line 10 to page 99, line 22 of the present specification and above-described Additional Experiments 1 and 2). In Example 1, Additional Experiment 1 and Additional Experiment 2, polymers 1,  $\alpha$  and  $\beta$  are respectively used as the hydrogenated copolymer.

The characteristics of polymer 1 are described at page 89, line 2 to page 91, line 21 of the present specification.

Polymer 1 is a hydrogenated copolymer which is obtained by hydrogenating an unhydrogenated block copolymer having a block configuration H-S-H, wherein each H independently represents a styrene polymer block and S represents a styrene/butadiene copolymer block (see page 89, line 3 to page 91, line 14 of the present specification). The copolymer block S has a vinyl bond content of 20 % as measured with respect to butadiene monomer units (see page 90, lines 18-21 of the present specification). Also, polymer 1 has a styrene monomer unit (vinyl aromatic monomer unit) content of 52 % by weight (see page 90, lines 16-17 of the present specification). (It should be noted that, as described at page 20, lines 2-9 of the present specification, the content of the vinyl aromatic monomer units in the hydrogenated copolymer is approximately equal to the content of the vinyl aromatic monomer units in the unhydrogenated copolymer and, therefore,

the content of the vinyl aromatic monomer units in the unhydrogenated copolymer can be used as the content of the vinyl aromatic monomer units in the hydrogenated copolymer.) Further, in a dynamic viscoelastic spectrum obtained with respect to polymer 1, a peak of loss tangent ( $\tan\delta$ ) is observed at  $-15^{\circ}\text{C}$  (see page 91, lines 16-18 of the present specification).

Based on the information on the characteristics of polymer 1, and the information on the characteristics of polymers  $\alpha$  and  $\beta$  described in Additional Experiments 1 and 2, the following Table A is obtained:

Table A

	Polymer 1	Polymer $\alpha$	Polymer $\beta$
Block configuration	H-S-H	H-S-H	H-S-H
Vinyl bond content (%)	20	20	19
Styrene content (%) of the hydrogenated copolymer	52	52	59
Peak ( $^{\circ}\text{C}$ ) of loss tangent ( $\tan\delta$ )	-15	-42	12

Notes:

(1) "Block configuration" means the block configuration of the unhydrogenated block copolymer from which the hydrogenated copolymer is produced by hydrogenation. In these block configurations, each H independently represents a styrene polymer block and each S independently represents a styrene/butadiene copolymer block.

(2) "Vinyl bond content" means the vinyl bond content of the copolymer block S (as measured with respect to butadiene monomer units) contained in the unhydrogenated block copolymer.

Properties of the polymer foam produced in Example 1 are shown in Table 1 appearing at page 104 of the present specification. Based on the information on the properties of the polymer foam produced in Example 1, and the information on the properties of the polymer foams produced in Additional Experiments 1 and 2, the following Table B is obtained:

Table B

	Example 1 (in which polymer 1 is used)	Additional Ex- periment 1 (in which polymer $\alpha$ is used)	Additional Ex- periment 2 (in which polymer $\beta$ is used)
Specific gravity	0.23	0.23	0.23
Hardness at 22 °C	40	50	45
Hardness at -10 °C	50	49	70
Impact resilience (%)	29	46	5
Compression set (%)	44	43	55

Notes:

- (1) The smaller the hardness of the polymer foam at 22 °C, the better the flexibility of the polymer foam (see page 85, lines 6-7 of the present specification).
- (2) The smaller the hardness of the polymer foam at -10 °C, the better the low temperature characteristics of the polymer foam (see page 85, lines 8-10 of the present specification).
- (3) The smaller the impact resilience of the polymer foam, the better the shock-absorbing property of the polymer foam (see page 87, lines 16-18 of the present specification).
- (4) The smaller the compression set of the polymer foam, the better the compression set resistance of the polymer foam (see page 86, lines 18-20 of the present specification).

Observations are made below with reference to Tables A and B above.

At the outset, it should be noted that, among polymers 1,  $\alpha$  and  $\beta$ , polymer 1 is encompassed by the hydrogenated copolymer (A) recited in amended claim 1, whereas polymers  $\alpha$  and  $\beta$  are not encompassed by the hydrogenated copolymer (A) recited in amended claim 1. On this point, explanation is given below.

The hydrogenated copolymer (A) recited in amended claim 1 is obtained by hydrogenating an unhydrogenated copolymer. The hydrogenated copolymer (A) has the following features (I) to (IV) :

(I) The unhydrogenated copolymer from which the hydrogenated copolymer (A) is obtained by hydrogenation is a block copolymer containing at least one copolymer block S comprised of vinyl aromatic monomer units and conjugated diene monomer units and at least one homopolymer block H of vinyl aromatic monomer units, and has a specific block configuration, such as "H-S-H".

(II) The at least one copolymer block S has a vinyl bond content of from 5 % to less than 40 % as measured with re-

spect to conjugated diene monomer units.

(III) The hydrogenated copolymer (A) has a content of the vinyl aromatic monomer units of from more than 40 % by weight to 60 % by weight, based on the weight of the hydrogenated copolymer (A).

(IV) At least one peak of loss tangent ( $\tan\delta$ ) is observed at -40 °C to lower than -10 °C in a dynamic viscoelastic spectrum obtained with respect to the hydrogenated copolymer (A).

As seen from Table A above, polymer 1 has all of features (I) to (IV). On the other hand, polymer  $\alpha$  has features (I) to (III), but does not have feature (IV); in polymer  $\alpha$ , the peak of loss tangent is observed at -42 °C, which is lower than the lower limit (-40 °C) of the range defined in feature (IV). Further, polymer  $\beta$  has features (I) to (III), but does not have feature (IV); in polymer  $\beta$ , the peak of loss tangent is observed at 12 °C, which is higher than the upper limit (-10 °C) of the range defined in feature (IV).

As explained above, the polymer foams in Additional Experiments 1 and 2 are produced in substantially the same manner as in the production of the polymer foam in Example 1,

except that, polymers  $\alpha$  and  $\beta$  are respectively used as the hydrogenated copolymer in place of polymer 1. Therefore, the differences in properties between the polymer foams produced in Example 1 and Additional Experiments 1 and 2 are caused due to the differences in characteristics between the hydrogenated copolymers used in Example 1 and Additional Experiments 1 and 2.

As seen from Table B above, the polymer foam of Example 1 exhibits excellent properties with respect to all of flexibility, low temperature characteristics (such as flexibility at low temperatures), shock-absorbing property (low impact resilience) and compression set resistance. The excellent properties of the polymer foam of Example 1 is achieved by the use of polymer 1 (which is encompassed by the hydrogenated copolymer (A) recited in amended claim 1) for producing the polymer foam.

On the other hand, the polymer foam of Additional Experiment 1 exhibits excellent properties with respect to flexibility, low temperature characteristics (such as flexibility at low temperatures) and compression set resistance, but exhibits poor shock-absorbing property as compared to the case of the polymer foam of Example 1. Specifically, the polymer foam of Additional Experiment 1 exhibits an impact

resilience of 46 %, which is much higher than the impact resilience of 29 % in the case of the polymer foam of Example 1. The poor property of the polymer foam of Additional Experiment 1 is caused due to the use of polymer  $\alpha$  for producing the polymer foam. Polymer  $\alpha$  is not encompassed by the hydrogenated copolymer (A) recited in amended claim 1 in that the peak of loss tangent is observed at -42 °C, which is lower than the lower limit (-40 °C) of the presently claimed range.

Further, the polymer foam of Additional Experiment 2 exhibits excellent properties with respect to flexibility, shock-absorbing property (low impact resilience) and compression set resistance, but exhibits poor low temperature characteristics (such as flexibility at low temperatures) as compared to the case of the polymer foam of Example 1. Specifically, the polymer foam of Additional Experiment 2 exhibits a hardness of 70 at -10 °C, which is much higher than the hardness of 50 at -10 °C in the case of the polymer foam of Example 1. The poor property of the polymer foam of Additional Experiment 2 is caused due to the use of polymer  $\beta$  for producing the polymer foam. Polymer  $\beta$  is not encompassed by the hydrogenated copolymer (A) recited in amended claim 1 in that the peak of loss tangent is observed at 12 °C, which is higher than the upper limit (-10 °C) of the presently claimed

range.

#### 4. Conclusion

From the observations, it can be fairly concluded:

- (1) that the polymer foam of Example 1 exhibits excellent properties with respect to all of flexibility, low temperature characteristics (such as flexibility at low temperatures), shock-absorbing property (low impact resilience) and compression set resistance, because the polymer foam is produced using polymer 1 encompassed by the hydrogenated copolymer (A) recited in amended claim 1;
- (2) that, on the other hand, the polymer foam of Additional Experiment 1 exhibits poor shock-absorbing property, because the polymer foam is produced using polymer  $\alpha$ , which is not encompassed by the hydrogenated copolymer (A) recited in amended claim 1 in that the peak of loss tangent is observed at  $-42^{\circ}\text{C}$ , which is lower than the lower limit ( $-40^{\circ}\text{C}$ ) of the presently claimed range;
- (3) that, further, the polymer foam of Additional Experiment 2 exhibits poor low temperature characteristics (such as flexibility at low temperatures), because the polymer foam is produced using polymer  $\beta$ , which is not encompassed by the hy-

drogenated copolymer (A) recited in amended claim 1 in that the peak of loss tangent is observed at 12 °C, which is higher than the upper limit (-10 °C) of the presently claimed range; and

(4) that, therefore, by the use of the hydrogenated copolymer (A) recited in amended claim 1, there can for the first time be obtained a polymer foam which exhibits excellent properties with respect to all of flexibility, low temperature characteristics (such as flexibility at low temperatures), shock-absorbing property (low impact resilience) and compression set resistance.

## The Rise of the Result-Effective Variable

By Moshe K. Wilensky

One interesting development in patent prosecution since the Supreme Court issued its ruling in *KSR* has been the increasingly notable use by examiners of the result-effective variable doctrine in rejections. This article will briefly discuss what a result-effective variable is, examine why it is being used more regularly in rejections, present potential arguments for overcoming rejections of this type, and indicate the likely direction the doctrine may take in the future.

### What Is a Result-Effective Variable Rejection?

A result-effective variable rejection (or optimization rejection)<sup>1</sup> asserts that it would be obvious to "optimize" a prior art reference, which discloses the *existence* of a feature, to disclose a *specific amount or value* of that feature. The MPEP states, "A particular parameter must be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before determination of the optimum or workable ranges of said variable might be characterized as routine experimentation."<sup>2</sup>

To illustrate the concept, consider the following hypothetical. A claim recites a method of making a widget. One of the claimed steps recites treating the widget with a 5% solution of chemical X. The specification explains that the 5% solution is used to inhibit rusting. The examiner rejects the claim, under 35 U.S.C. §.103(a), using a reference that discloses treating an identical widget with a solution of chemical X but does not explicitly disclose using a 5% solution. The determination of whether this rejection is valid hinges upon whether the prior art indicates that it is known to use chemical X to inhibit rusting.

If the applied reference discloses that the solution of chemical X is applied to inhibit rusting, then chemical X is a result-effective variable. Namely, the reference discloses a parameter (chemical X) that can be applied in varying amounts (a solution of 1-100%) to achieve a recognized result (rustproofing). In such a case, it would be obvious to conduct routine experimentation to determine the percentage of chemical X in the disclosed solution that *best* inhibits rusting.

However, suppose the prior art only discloses that chemical X is added to make the surface scratch resistant. In such a case, chemical X is not a result-effective variable because the prior art fails to demonstrate it was known to apply chemical X for the proper "known result." The applicant can traverse the rejection by arguing that routine experimentation would only determine

the solution of chemical X that would result in the *most scratch-resistant* widget possible, but not necessarily the most *rustproof*.

### Result-Effective Variable Doctrine and KSR

*Chisum on Patents* described the result-effective variable doctrine as an exception carved into the prohibition against "obvious-to-try" rejections.<sup>3</sup> Because it was an exception, the courts narrowly construed the doctrine, and optimization rejections were fairly rare before KSR. However, in *KSR v. Teleflex*, the Supreme Court relaxed the degree of proof needed to uphold an obviousness rejection and held that "obvious to try" rejections are proper.<sup>4</sup> Thus, it is currently unclear whether the previous limitations on result-effective variable rejections are still good precedent. Indeed, it is even unclear whether the result-effective variable doctrine will remain a separate doctrine, or simply be merged into the case law surrounding the obvious-to-try standard, as will be discussed below.

In light of these developments, examiners appear to be operating under the presumption that the requirements for demonstrating that a feature is a result-effective variable also have been relaxed. Specifically, recent office actions have shown a spike in optimization rejections. Additionally, examiners have indicated in personal interviews they are interpreting the doctrine more liberally.

### Traversing Result-Effective Variable Rejections Based on Current Precedent

The MPEP itself describes one method for traversing an optimization rejection. Specifically, the MPEP states the rejection can be overcome if the applicant can demonstrate the recited range resulted in "unexpected good results."<sup>5</sup> However, showing unexpectedly good results is only necessary if the office action presents a proper *prima facie* optimization rejection. Therefore, another way to traverse an optimization rejection is by arguing that the office action has failed to properly demonstrate the feature is a result-effective variable.

Below are two examples of recent U.S. Patent and Trademark Office (USPTO) rejections that improperly asserted a feature was a result-effective variable. They are illustrative in understanding how the USPTO is currently applying this doctrine and some potential arguments for traversing similar rejections.

#### *Example 1: Dimensions of a Slit*

In this example, the claim recited a series of "slits" in several long tubes. The slits were designed to filter out particulate matter from air moving through the tubes. The claim recited that the "width of each slit is in a range from 0.2 to 1mm, and a length of each slit is from 1mm to . . . 30mm." The office action asserted Reference A disclosed a tube with a slit but acknowledged that Reference A did not disclose the specifically recited dimensions. The relevant text of the office action read:

Although [Reference A] does not specifically teach the claimed dimensions for each slit, the claimed dimensions do not confer patentability to the claim, since the precise dimensions for each slit would have been considered a result effective variable by one of ordinary skill in the art, as evidenced by [Reference

B]. For instance, [Reference B] teaches a [tube] comprising slit in the form of gas blow holes 6 . . . "the collecting efficiency [was] measured in relation to the opening area of the exhaust has blowing holes 6 . . . as a result the proper opening area of the blowing holes 6 was 0.5 to 10% of the total opening area of the passages." (Quoting Reference B)

The office action concluded that

one having ordinary skill would have routinely optimized the dimensions of each slit to achieve the desired opening area for each slit, in order to obtain the desired amount of [collection efficiency] in the system.

This rejection was traversed by arguing that the rejection improperly asserted that the recited dimensions were a *single* result-effective variable. The response argued the rejection failed to analyze whether the length and the width *independently* qualified as result-effective variables. Instead, the office action had treated both length and width as a single variable.

The response pointed out that the specification showed that the values for the width and length were chosen based on different criteria. Only the width had been chosen to maximize collection efficiency. This traversal was persuasive, and in a future office action the examiner conducted two independent analyses, independently asserting that width and length were both individually result-effective variables. The subsequent Office action was also overcome and the application allowed.

#### *Example 2: Uniform Distribution of Fibers in a Composite Material*

Another interesting case involved a claim reciting a composite material having carbon nanofibers "uniformly dispersed" in an elastomer. The office action rejected the claim by first asserting that all of the claim elements other than the uniform dispersion were disclosed by the prior art. The USPTO then asserted that

dispersion of the fibrils is a result effective variable which is related to the surface properties of the modified fibers and/or the compatibility of the polymer with the functional groups. Therefore, the person of ordinary skill in the art would have been able to select the functional groups of the modified fibrils in order to arrive at fibrils which would be able to be dispersed in the polymer systems.

As a preliminary matter, this case is interesting for demonstrating that examiners frequently misapply the term "result-effective variable." In this office action, the examiner asserts that "dispersion" is a result-effective variable. However, a result-effective variable is a parameter that affects a known result. As seen in the quoted text above, dispersion is not the parameter. Rather, dispersion is the alleged *known result*.<sup>6</sup>

The text of the office action also contains all the information needed to traverse the rejection. The office action states that the surface properties of the fibers *and/or* the compatibility of the polymer affect the dispersion. However, current case law states a parameter is not a result-effective variable if multiple other parameters can affect the "recognized result."<sup>6</sup>

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In *In re Antonie* the court held that the prior art did not recognize that treatment capacity (the alleged "recognized result") of a wastewater treatment tank was a function of tank volume (the alleged result-effective variable).<sup>7</sup> The court stated that "such functionality can only be determined from data representing either efficiency at varying tank volume [with] fixed throughput and fixed contactor area or throughput at varying tank volumes [with] fixed efficiency and fixed contactor area." In other words, the court held that if the applied reference disclosed that the recited factor was among *several known factors* that might affect a given result, the recited factor was not a result-effective variable.<sup>8</sup>

In this case, by using the phrase "and/or" the office action appears to concede that two different variables can affect dispersion. Therefore, dispersion is not affected by *one*, and only one, variable. Thus, under the holding of *In re Antonie*, it would not be obvious to optimize dispersion through routine experimentation.

#### The Future of the Result-Effective Variable Doctrine

The above examples demonstrate two potential ways of traversing an optimization rejection. However, based on current post-KSR trends, the effectiveness of these methods may be lessened in the future. To date, the Federal Circuit has not directly addressed a result-effective variable case since the KSR decision. However, dicta in the case of *Pfizer, Inc. v.*

*Apotex, Inc.* may shed some light on the direction the Federal Circuit may take this branch of law in the future.<sup>9</sup>

The decision in *Pfizer* contained an extensive analysis of whether it would have been obvious to improve the chemical stability of a hypertension drug by adding besylate salt.<sup>10</sup> Apotex maintained that Pfizer had chosen besylate salt from among a large number of potential chemical salts that were known to improve chemical stability. Apotex therefore asserted that the choice of besylate salt was obvious because Pfizer had merely engaged in routine experimentation to determine which salt best improved the stability of the drug in capsule form.

The *Pfizer* decision addressed the difficulty in distinguishing between an obvious feature based on "routine experimentation" and genuine novelty. The court analogized the case to that of discovering an optimum value of a result-effective variable.<sup>11</sup> In particular, the court stated that "this is not [a] case where there are 'numerous parameters' to try . . . [r]ather, the only parameter to be varied is the anion with which to make the . . . salt."<sup>12</sup> In effect, the court held that just as it is obvious to test what percentage of chemical X best inhibits rust, it is equally obvious to test which of several known salts best improves chemical stability.

The *Pfizer* decision suggests that future developments for optimization rejections will likely be tied to future developments to the obvious-to-try standard. Thus, a short summary

of these developments seems appropriate. The MPEP states that the prior art must suggest a "finite number" of "identified predictable solutions" such that one of ordinary skill would have had a "reasonable expectation of success" for solving a known problem.<sup>13</sup>

Most of the development to the result-effective variable doctrine will likely derive from future interpretations of the phrases "predictable solutions" and "reasonable expectation of success." These phrases effectively inquire as to how much experimentation it would take before one of ordinary skill in the art would expect success. This question also lies at the heart of the result-effective variable doctrine.

For example, it is the expected volume of experimentation that drives the policy behind the "one variable" doctrine of *In re Antonie*. Using the widget analogy to illustrate, it takes 100 tests to determine how much chemical X best inhibits rusting of a widget. Namely, we dip a widget in 100 solutions each having from 1–100% of chemical X and see which one rusts last. But if we needed to test a widget coated with two chemicals (each in a solution from 1–100%), we would need to run 10,000 tests to determine how each variable affects the rustproofing.

KSR effectively gave the USPTO more leeway in the amount of hypothetical experimentation the hypothetical person of ordinary skill would be allowed to undertake. So to, the courts are likely to allow the PTO more leeway in declaring that it would be obvious to

optimize a result-effective variable. The first likely casualty of this shift in direction will be the rigid holding of *In re Antonie* that only a single variable can affect a result. In fact, based on example 2 above, examiners appear to already be moving in this direction.

However, the Federal Circuit is already moving to curtail the limits of obviousness using the "predictable solutions" and "reasonable expectation" requirements. The Federal Circuit recently overturned an obvious-to-try rejection on the grounds that one of ordinary skill could not have had a reasonable expectation of success due to the "unpredictable" nature of the field.<sup>14</sup> Thus, the most effective arguments for traversing future optimization rejections may lie in convincing the examiner that it would take an excessively large number of tests to optimize a feature. Such arguments may be based upon the number of variables affecting the "known result" and/or the level of unpredictability in the art.

Another interesting development is evident in example 2 and several other recent office actions. The result-effective variable doctrine was traditionally used to prove that it would be obvious to optimize a claimed feature to a specific *value or range*. However, in example 2, the claim did not recite any ranges or values. The claim merely recited "uniform dispersion." The office action chose to treat the concept of dispersion as a value.

Continued on 4!

#### Endnotes

1. C. Gaz. pt. I, § 4787 (Dec. 24, 1994).
2. [1999] 84 C.P.R. (3d) 129, *aff'd*, [1999] 87 C.P.R. (3d) 293 (Can.).
3. [1999] 87 C.P.R. (3d) 293, at ¶ 15 (Can.).
4. *Id.* at ¶ 17.
5. C. Gaz. pt. II, vol. 140, no. 21, at 1495.
6. Guidance Document Data Protection under C.08.004.1 of the Food and Drug Regulations, at 2.
7. C. Gaz. pt. II, vol. 140, no. 21, at 1496; Guidance Document Data Protection under C.08.004.1 of the Food and Drug Regulations, at 3.
8. 21 U.S.C. § 355.
9. 21 C.F.R. § 314.108.
10. Guidance Document Data Protection under C.08.004.1 of the Food and Drug Regulations, at 6.
11. *Id.*
12. *Id.*
13. *Id.* at 7.
14. 21 U.S.C. § 355; 21 C.F.R. § 314.108.
15. 21 U.S.C. § 360aa; 21 C.F.R. § 316.
16. 21 U.S.C. §§ 355a, 505(A).
17. Guidance Document Data Protection under C.08.004.1 of the Food and Drug Regulations, at 4, 9.
18. 2008 FC 1379, *aff'd*, 2009 FCA 134 (Can.).
19. Merck Frosst Canada Inc. v. Canada (Minister of Health), [1997] F.C.J. No. 1847 (F.C.), *aff'd*, [1999] F.C.J. No. 1536 (Can.).
20. Food and Drug Regulations, C.R.C. c. 870, C.08.004.1.
21. R.S.C., 1985, c. F-27.
22. C. Gaz. pt. II, vol. 140, no. 21, at 1495–96.

## Challenge Dismissed

This past summer the Federal Court dismissed the challenge to the validity of Canada's current data protection regulations. The court held the regulations are consistent with both NAFTA and TRIPS, noting, interestingly, that NAFTA identifies a market exclusivity protection mechanism. The court found that the innovator's ANDS data meet the definition of secret or undisclosed information under both NAFTA and TRIPS. While the information may not be secret in all respects, in its compilation it is unique to the innovator drug manufacturer, has been assembled with considerable effort, and has value. The court also found that in effect a generic company relies on the innovator's work in securing an ANDS approval.

In regard to the constitutional challenge, the court found the regulations to be a valid exercise of the federal power to regulate trade and commerce, in that the implementation of TRIPS and NAFTA has a national dimension relating to Canada's ability to participate in world trade.

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In effect, the examiner asserted that it was possible to optimize material choices as result-effective variables. This type of approach dovetails with the *Pfizer* decision in which the choice of salt was almost treated as a matter of routine optimization also. It remains to be seen whether the USPTO and the courts will allow the result-effective variable doctrine to be merged with the obvious-to-try doctrine, or whether the line of demarcation between the two types of rejections will be maintained.

As noted earlier, *Chisum* described the routine optimization of variables as a modification to the obvious-to-try ban. However, in light of *KSR*, it is no longer necessary to modify an obvious-to-try rejection anymore. Indeed, an argument could be made that the limitations on optimization rejections are already embodied by the current USPTO guidelines for demonstrating a feature is obvious to try.

For example, the MPEP requires that the prior art identify a problem to be solved and some known solutions, just as a result-effective variable must affect a result recognized by the prior art. Additionally, the MPEP limits an examiner to a finite number of known solutions and suggests that we will expect a reasonable expectation of success, which may only be a euphemism for limiting the hypothetical "person of ordinary skill in the art" to routine experimentation with the finite number of known solutions.

However, for the moment, the precedent of *In re Antonie*

and the other limitations on result-effective variables remain good law. As such, traversing optimization rejections using the approaches discussed above will likely work for the immediate future. ■

#### Endnotes

1. The terms "result-effective variable" and "optimization" are frequently used interchangeably in office actions making rejections of this type.
2. MPEP § 2144.05(II)(B).
3. CHISUM ON PATENTS § 5.04[1][f][iv].
4. 550 U.S. 398 (2007).
5. MPEP § 2144.05(III).
6. *In re Antonie*, 559 F.2d 618, 620 (C.C.P.A. 1977).
7. *Id.*
8. *Id.*
9. 480 F.3d 1348 (Fed. Cir. 2007), en banc appeal denied May 21, 2007. The procedural history of *Pfizer* is particularly relevant to its predictive status. *Pfizer* was decided by the Federal Circuit after the Supreme Court had granted certiorari in *KSR*, but before the *KSR* decision was handed down. Furthermore, the Federal Circuit declined to rehear *Pfizer* en banc after *KSR* was decided, thus lending a veneer of post-*KSR* persuasiveness to the decision.
10. *Id.*
11. *Id.*
12. *Id.* at 1366.
13. MPEP § 2143(E).
14. Eisai Co., Ltd. v. Dr. Reddy's Labs., Inc., 87 U.S.P.Q.2d 1452, 1457 (Fed. Cir. 2008). The court held the process of determining DNA sequences from known proteins was extremely unpredictable in the level of time and effort necessary to achieve success.